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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,404	03/04/2002	John N. Feder	8907-098-999	9646

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PENNIE & EDMONDS LLP
1155 Avenue of Americas
New York, NY 10036-2711

EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/092,404	Applicant(s) FEDER ET AL	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-9 is/are allowed.
- 6) ☒ Claim(s) 10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 09/094,964, which is a continuation-in-part of U.S. Application Serial Number 08/876,010.

Claims 1-6 have been canceled previously.

Claims 10 and 11 have been added.

Claims 7-11 are currently pending.

In view of Applicant's amendment filed February 9, 2004 all outstanding grounds of rejection have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over either U.S. Patent No. 6,025,130 to Thomas et al (A on form PTO-892) or U.S. Patent No. 6,140,305 to Thomas et al (B on form PTO-892).

The '130 and '305 patents each disclose wild type and mutant forms of the HH protein, which is the same protein disclosed instantly as HFE. For the purpose of the present discussion, the elements will be addressed as they appear in the '305 patent. Applicant is reminded that the term "having" is interpreted as an open term consistent with the recitation of "comprising" and the recitation of "having" in these claims therefore opens the claims up to include unrecited elements including the additional amino acid residues of the full-length protein. The '305 patent teaches the HH gene product of SEQ ID NO: 2 as a 348 amino acid residue polypeptide having instant SEQ ID NO: 1 as amino acid residues 1-276 [instant

claim 7]. The '305 patent also teaches the mutant HH gene product of SEQ ID NO: 6 as a 348 amino acid residue polypeptide having instant SEQ ID NO: 2 as amino acid residues 23-298 [instant claim 8].

The '305 patent further teaches that the HH gene product possesses significant homology to HLA Class I molecules which are known to interact with β_2 microglobulin and that β_2 microglobulin knock-out mice developed symptoms of iron overload disease (column 14, lines 28-54 in particular) which is a phenocopy of human hemochromatosis (column 24, lines 4-13 in particular). The '305 patent further teaches that a mutation in the β_2 microglobulin binding domain of the HH gene product predicted to ablate binding of the gene product to β_2 microglobulin was common to the majority of patients with human hemochromatosis (column 14, lines 28-54 in particular). The '305 patent teaches that when this binding is lost, the protein no longer is located on the cell-surface (column 24, lines 4-13 in particular).

The '305 patent also teaches that the HH gene product can be purified by conventional affinity chromatography techniques based on its homology with MHC Class I molecules. The '305 patent teaches immobilization of β_2 microglobulin on an inert matrix for purification of the HH gene product (column 24, lines 15-48 in particular). Accordingly, the purification procedure results in the production of a composition comprising an HH gene product, or HFE polypeptide, having SEQ ID NO: 1 or 2 and a full length, wild type human β_2 microglobulin.

The prior art teachings do not specifically teach such a composition in a form "suitable for administration to a subject. However, it would have been well within the purview of one of ordinary skill in the art to subject the composition obtained from the aforementioned purification procedure to an exchange of buffer, for example, by dialysis. It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to exchange the purification buffer with one suitable for administration to a subject in order to administer the composition to β_2 microglobulin knock-out mice. One would have been motivated, with a reasonable expectation of success, to perform this buffer exchange and administer the composition to a knock-out mouse by the teachings of the '305 patent that the HH gene product possesses significant homology to HLA Class I molecules, that β_2 microglobulin knock-out mice developed symptoms of iron overload disease and that a mutation in the β_2 microglobulin binding domain of the HH gene product predicted to ablate binding of the gene product to β_2 microglobulin was common to the majority of patients with human hemochromatosis.

Conclusion

2. Claims 7-9 are allowed.

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3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

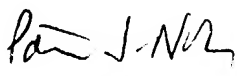
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. 
Patent Examiner
May 5, 2004


PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

5/13/04